

DAI Jinliang vs China National Intellectual Property Administration (CNIPA),

Administrative Dispute over Invalidation of Invention Patent:

(Intellectual Property Court of the Supreme People's Court of China (SPC), (2019) SPC IP
Admin. Final 16)

Prepared by the Intellectual Property Court of SPC

Summary

In this case, the SPC pointed out that in terms of inventiveness assessment, if a person skilled in the art cannot obtain the biological material claimed in the patent by repeating the preparation method in the reference document, then the claimed biological material shall be identified as being not disclosed by such reference document.

Facts

This case concerns an invention patent named *Pseudomonas Aeruginosa Mannose-Sensitive Hemagglutinin (PA-MSHA) Pilus Strain* and relates to the field of microorganism genetic engineering technology. The patentee is *Beijing Wanteer Biological Pharmaceutical Co., Ltd.* *DAI Jinliang* submitted a request for invalidation of the patent to CNIPA asserting that the patent claims are not inventive. CNIPA maintained the validity of the patent after re-examination. *DAI Jinliang* was not satisfied with the decision and filed an administrative lawsuit with Beijing Intellectual Property Court, which rendered its judgment to uphold CNIPA's re-examination decision. *DAI Jinliang* then appealed to the Intellectual Property Court of the Supreme People's Court. The main ground asserted by *DAI Jinliang* is that the bacterial strains disclosed in the patent and Evidence 1 have identical bacterial traits, both having all the bacterial traits of *Pseudomonas aeruginosa*; and Evidence 1 has completely disclosed all technical information and method of obtaining the mannose-sensitive hemagglutinin pilus strain. According to Evidence 1, or Evidence 1 in combination with other evidence, a person skilled in the art can obtain the aforesaid mannose-sensitive hemagglutinin pilus strain, and therefore the patent in dispute lacks inventiveness.

Legal Issues

Article 22(1) of the *Patent Law of the People's Republic of China* stipulates that any invention or utility model for which patent may be granted must possess novelty, inventiveness and practicability. Article 22(3) stipulates that inventiveness means that, as compared with the technology existing before the date of filing, the invention has prominent substantive features (i.e. a legal concept vis-à-vis and equivalent to non-obviousness requirement in other jurisdictions) and represents a notable progress. Article 24(1) of the *Detailed Rules for the Implementation of the Patent Law of the People's Republic of China* stipulates that where an invention for which a patent is applied for concerns a new biological material which is not available to the public and

cannot be described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art, the applicants shall, deposit a sample of the biological material before or at the latest on the date of filing (or the priority date where priority is claimed).

Based on these legal provisions, the SPC held that assessing the inventiveness of patent applications concerning biological materials would include if the biological material as claimed to be patented is prepared by a non-reproducible means such as screening, mutation, etc., and can bring about positive effect and has been deposited. While the reference document only disclosed an identical or similar preparation method by means of screening, mutation and the like, it failed to deposit the biological material prepared. In such a case a person skilled in the art cannot obtain the biological material claimed in the patent by repeating the preparation method in the reference document. Hence, the biological material claimed in the patent shall not be deemed as disclosed by the reference document. In circumstances where there is no evidence showing that a person skilled in the art can obtain the biological material via other means or that a person skilled in the art has motivations to improve the preparation method for the sake of obtaining the biological material, the biological material as claimed in the patent application would have inventiveness as opposed to the technical solution disclosed in the reference document.

In this case, Evidence 1 disclosed a method for obtaining a *pseudomonas aeruginosa* pilus strain and the characteristics thereof. Evidence 1 also recorded a method for obtaining a bacterial strain substantially identical to the invention, and said bacterial strain also has mannose-sensitive hemagglutinin pilus (MSHA). However, Claim 1 of the patent recorded the Deposit Number of the bacterial strain, CGMCC0190, while Evidence 1 did not disclose that the bacterial strain was deposited, and did not contain any depository information. At this point, one shall not simply regard the presence or absence of deposit numbers as the distinguishing feature for identification. Instead, one should take into consideration the extent of disclosure of the bacterial strain and the obtainability of said bacterial strain as described by Evidence 1 therein, and therefore assess whether a person skilled in the art can obtain the said bacterial strain or has the motivations to prepare and obtain the said bacterial strain according to Evidence 1.

Firstly, Evidence 1 did not disclose the depository information of the *pseudomonas aeruginosa* MSHA pilus strain and did not record the commercially available channel or the distribution channel. As a result, there is no evidence showing that the bacterial strain of Evidence 1 is obtainable by the public in a form of goods or products that would thus become prior art. Secondly, the strain construction method disclosed in Evidence 1 includes a plurality of randomized and incidental factors, which include the randomization of the source of wild-type strain, randomization of the attenuated process, randomization of the genetic engineering and the screening method. Therefore, even if the information such as conditions, processes and the like of these steps are clearly described, the same result cannot be affirmatively obtained by repeating the steps. Finally, the immunogenicity of the strain is recorded in the patent specification, confirming its positive effect. In view of the above, the patent has prominent substantive features and represents remarkable progress as opposed to Evidence 1, and therefore meets the criterion of inventiveness.

Points of Significance

The patented bacterial strain has been deposited in accordance with the law, while the prior art did not disclose the depository information of the bacterial strain. Under such circumstances, one shall not simply regard the presence or absence of the depository number as distinguishing feature, but shall take into consideration the extent of disclosure of the bacterial strain and the obtainability of the said bacterial strain as described by the prior art therein, so as to assess whether a person skilled in the art can obtain the said bacterial strain or has motivations to prepare and obtain the said bacterial strain according to the description in prior art.

Key Words

Inventiveness; deposit of biological material; microorganism.

PDF version of the full text of the judgment in Chinese is available upon request.